MAY 1 2013

510(k) Summary

ADMINISTRATIVE INFORMATION

Manufacturer Name:	X-spine Systems, Inc. 452 Alexandersville Rd. Miamisburg, OH 45342 Telephone (937) 847-8400 FAX (937) 847-8410
Official Contact:	David Kirschman, M.D. Chief Medical Officer
Date Prepared:	December 19, 2012

DEVICE NAME

Trade/Proprietary Name:	Zygafix™ Spinal Facet Screw System
Common Name:	Facet Screw
Classification Name:	System, Facet Screw Spinal Device
Product Code:	MRW
Device Class:	Unclassified

ESTABLISHMENT REGISTRATION NUMBER

The X-spine Systems, Inc. establishment registration number is 3005031160. The owner/ operator number for X-spine Systems, Inc. is 9063903.

INTENDED USE

The X-spine Systems, Inc. Zygafix Spinal Facet Screw System is intended for posterior fixation to the lumbar spine (L1 to S1 inclusive). The system is intended for bilateral, transfacet fixation of the facet joint in order to provide stability for fusion. The system is intended for use with only autogenous bone graft material. The system is indicated for posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels:

- Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies),
- Degenerative disease of the facets with pain and/or instability on plain flexion and extension lateral radiographs where there is movement of the vertebral bodies relative to each other of more than 4mm,

- Trauma (i.e., fractures and/or dislocations),
- Spondylolisthesis,
- Spondylolysis,
- Pseudoarthrosis and/or failed previous fusions.

DEVICE DESCRIPTION

The X-spine Zygafix Spinal Facet Screw System is designed to provide bilateral, transfacet fixation of the spinal facet joint in the lumbar spine. The system consists of titanium alloy, cannulated bone screws that are available in various lengths and thread configurations to account for variations in patient anatomy. Each screw option contains axial fenestrations to allow the optional packing of bone graft. The screws are manufactured of medical grade Titanium alloy (Ti6Al4V) that complies with ASTM F136.

This system is not to be used with bone cement. The safety and efficacy of using bone cement with this system has not been established.

The implant components are provided clean and non-sterile. These devices are sterilized by a healthcare professional using a Steam Autoclave in accordance with the instructions for use provided by X-spine Systems Inc., as well as the instructions provided by the manufacturer of the Autoclave.

EQUIVALENCE TO MARKETED PRODUCT

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Zygafix Spinal Facet Screw System is substantially equivalent to the predicate device based on a comparison including the following characteristics:

- FDA Product Code
- Intended Uses
- Surgical Approach
- Anatomical Region
- Implant Materials
- Product Dimensions
- Mechanical Performance

PREDICATE DEVICES

- X-spine Systems, Inc. - Fixcet Spinal Facet Screw System (K100154)
- SpineFrontier, Inc. – Chameleon Fixation System (K071420)

PERFORMANCE DATA

The implant components were tested using the following standards:

ASTM F543 – *Standard Specification and Test Methods for Metallic Bone Screws*

- Annex 1 (A1) - Test Method for Determining the Torsional Properties of Metallic Bone Screws
- Annex 2 (A2) - Test Method for the Driving Torque of Medical Bone Screws
- Annex 3 (A3) - Test Method for Determining the Axial Pullout Strength of Medical Bone Screws
- Annex 4 (A4) – Test Method for Determining the Self-Tapping Performance of Self-Tapping Medical Bone Screws

ASTM F2193 – *Standard Specification and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System*

- Annex 4 (A4) - Test Method for Measuring the Static and Fatigue Bending Strength of Metallic Spinal Screws

In conclusion, biomechanical testing results indicate that the Zygafix Spinal Facet Screw System is substantially equivalent to predicate device performance and is capable of safely and effectively performing in accordance with its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 1, 2013

X-Spine Systems, Incorporated
% David Kirschman, M.D.
Chief Medical Officer
452 Alexandersville Road
Miamisburg, Ohio 45342

Re: K123932
Trade/Device Name: Zygafix™ Spinal Facet Screw System
Regulatory Class: Unclassified
Product Code: MRW
Dated: March 27, 2013
Received: March 28, 2013

Dear Dr. Kirschman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123932

Device Name: Zygafix™ Spinal Facet Screw System

Indications for Use:

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- Trauma (i.e., fractures and/or dislocations),
- Spondylolisthesis,
- Spondylolysis,
- Pseudoarthrosis and/or failed previous fusions.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)

Division of Orthopedic Devices

510(k) Number: K123932